REMARKS

This amendment is responsive to the Office Action of July 14, 2005. Claim 31 has been amended to include the limitations of claim 33, claim 33 has been cancelled, and the dependency of claims 34 and 36 has been updated. Claims 2-15, 17-32, and 34-39 are pending and are submitted for reconsideration.

The Office Action

Claims 2-15 and 17-39 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,285,902 (Kienzle) in view of U.S. Patent No. 4,577,629 (Martinez) further modified by U.S. Patent No. 4,370,983 (Lichtenstein).

Applicants' Traversal of the Rejections

The rejections under § 103 should be withdrawn because a *prima facie* case of obviousness has not been established. In particular, the cited references do not disclose, teach, or suggest all claimed features.

Claims 2-4

For example, claim 2 calls for a "disposable kit" that includes "an openable, transportable case" with surgical tools and a digital medium both "removably disposed in the case." The Office Action acknowledges that Kienzle and Martinez do not disclose disposable software or surgical tools that are part of a disposable kit. (Office Action at. p. 2-3.) The Office Action, however, contends that Lichtenstein discloses disposable modules (at col. 32, lines 27-52) and demonstrates that the functionality of disposing of software is well known. (Office Action at p. 3.) The Office Action concludes that it would have been obvious to "to apply the teachings of Martinez's disposable surgical tools and ***Lichtenstein's disposable software kit*** to the method and system of Kienzle" to reach the claimed invention. (Office Action at p. 3 (emphasis added).)

As explained in the Amendment filed April 28, 2005, Kienzle and Martinez do not teach or suggest a kit as called for in claim 2. Contrary to the assertion of the Office Action, Lichtenstein does not cure the deficiencies of Kienzle

and Martinez. By contrast, Lichtenstein discloses a fluid control module for use in "procedures involving the withdrawal, infusion, or extracorporeal circulation of fluid from or to a patient." (Lichtenstein at col. 2, lines 41-45.) The module (e.g., module 83 in Fig. 5) includes tubing "formed in a fixed pattern to provide a definite array of flow paths corresponding to the procedure for which it is designed." (Lichtenstein at col. 3, lines 5-10; col. 15, lines 51-53.) The module may be disposable "in order to decrease the possibility of patient-to-patient or patient-to-staff contamination." (Lichtenstein at col. 3, lines 11-13.) The module is controlled by a microcomputer and is "keyed to insure correspondence between the procedure for which the module is designed and the program inserted into the microcomputer for carrying out the procedure." (Lichtenstein at col. 4, line 27-31.) The module may also contain the program for carrying out the procedure. (Lichtenstein at col. 18, lines 21-28.)

The module 83 of Lichtenstein is not a kit as called for in claim 2. For example, the module 83 does not include an openable, transportable case . Moreover, Lichtenstein does not suggest surgical tools and a digital medium removably disposed in the case as called for in claim 2. In contrast, as shown in Fig. 5, the module 83 has a series of tubing for processing fluid taken from a patient. As explained in col. 17, lines 6-15, blood is taken from the patient through a tube 96, circulated through a tube 61, passed through a tube 97 to a column containing an adsorbent, returned through a tube 74 to a debubbler 98, and finally returned to the patient through a tube 100. The module 83 also includes a code 106 "indicating the nature of the procedure for which module 83 is constructed" and may contain a program (Lichtenstein at col. 17, lines 20-23; col. 18, lines 26-28.) There is no teaching or suggestion anywhere in Lichtenstein that the module 83 includes a kit having a case, that the module 83 includes surgical tools, or that any part of the module 83 (including a program on a digital medium) is removably disposed in a case. Thus, Lichtenstein does teach or suggest a disposable kit as called for in claim 2 and does not cure the deficiencies of Kienzle and Martinez.

"To establish a *prima facie* case of obviousness . . . ***all*** the claim limitations must be taught or suggested in the prior art" and "***[a]ll*** words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (emphasis added). Because the cited references (alone or in

combination) do not disclose a kit as called for in claim 2, the cited references do not teach or suggest all the features of the claimed invention. For at least this reason, reconsideration and withdrawal of the rejection of claim 2 and of dependent claims 3 and 4 are respectfully requested.

Claims 7-8

Claim 7 calls for a single-use kit that includes "a portable, openable housing" with surgical tools and a digital medium both "being removably disposed in the housing." The cited references do not teach or suggest a kit as called for in claim 7. None of the references alone, or in combination, suggest a kit including a digital medium and the other enumerated equipment in a labeled portable housing, which digital medium is a one-time use digital medium that contains a portion of image guided surgery software specific to the preselected procedure identified by the label. Reconsideration and withdrawal of the rejection of claim 7 and of dependent claim 8 are respectfully requested.

Claim 9

Claim 9 calls for a "disposable kit" that includes surgical tools and a digital medium both "being packaged in a common shipping unit from which the tools and digital medium are removable at the surgical site." The cited references do not teach or suggest a kit as called for in claim 9. Reconsideration and withdrawal of the rejection of claim 9 are respectfully requested.

Claim 10

Claim 10 calls for a "one-time-use kit" that includes "a shipping case" with surgical tools and a digital medium both "removably received in the shipping case." The cited references do not teach or fairly suggest a kit as called for in claim 10. Reconsideration and withdrawal of the rejection of claim 10 are respectfully requested.

Claim 11

Claim 11 calls for a "software-integrated kit" that includes "a common case" and surgical tools and a digital medium "both being removably disposed in the common case." The cited references do not teach or suggest a kit as called for in claim 11. Reconsideration and withdrawal of the rejection of claim 11 are respectfully requested.

Claims 23-29

Claim 23 calls for "providing a kit" that includes surgical tools and a digital medium and "removing the digital medium from the kit and inserting it into a processor" and "removing the surgical tools . . . from the kit." The cited references do not teach or suggest removing a digital medium from a kit and inserting into a processor. Reconsideration and withdrawal of the rejection of claim 23 and of dependent claims 24-29 are respectfully requested.

Claim 30

Claim 30 calls for "a surgical kit" that includes "a housing" with surgical tools and a digital media both "being removably disposed in the housing." Moreover, the kit includes medical appliances which are maintained sterile by being sterile packaging. The medical appliances are removable from the kit with their sterile packaging. An operator control in a sterile package is also removably disposed in the kits's housing. A digital medium which upgrades image guided surgery software is also removably disposed in the kit's housing. The cited references do not teach or suggest a kit as called for in claim 30. Reconsideration and withdrawal of the rejection of claim 30 are respectfully requested.

Claims 5, 6, 12-15, 17-22, 31, 32, and 34-39

The cited references (alone or in combination) also do not teach or suggest "a means for deactivating or encrypting the digital medium against reuse at the end of the surgical procedure" as called for in claim 5; "deactivating or encrypting the digital medium against reuse after the surgical procedure" as called for in claim 20; "a deactivator which deactivates the digital media against reuse at the end of an

image guided surgical procedure" as called for in claim 31; "a means for disabling the software from being reused to upgrade the computer after the preselected surgical procedure" as called for in claim 38; or "deactivating or encrypting the digital medium against reuse in the integrated computer" as called for in claim 39.

Nothing in Kienzle, Martinez, or Lichtenstein in any way teaches or suggests that a digital medium should be deactivated or encrypted against reuse or that software should be disabled from being reused, and the Office Action fails to even consider these limitations. "The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. . . . either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." MPEP § 2142.

The Lichtenstein system is a complex, expensive system. Disposal of the Lichtenstein system after one use could create problems for the manufacturer. The disposed device could (and likely would) be salvaged by a used medical equipment reprocessor, reprocessed (cleaned, sterilized, etc.), and sold to hospitals or other medical facilities in competition with the original manufacturer. With a complex, expensive system such as Lichtenstein's, the reprocessor would have a substantial cost advantage. Moreover, if the reprocessed device malfunctions or harms a patient, the original manufacturer may find itself on the wrong end of a product liability law suit. The value of the Lichtenstein product would be enhanced if the present application's teaching of deactivating software after one use were added to it. But, this concept is absent from the applied references.

Because the cited references do not teach or suggest deactivating or encrypting the digital medium against reuse as called for in claims 5, 20, 31, and 39 or disabling software from being reused as called for in claim 38, the cited references do not teach or suggest all the features of claims 5, 20, 31, 38, and 39. Thus, a *prima facie* case of obviousness has not been established. For at least this reason, reconsideration and withdrawal of the rejection of claim 5 and dependent claims 6 and 12-15; claim 20 and dependent claims 17-19, 21, and 22; claim 31 and dependent claims 32 and 34-37; claim 38; and claim 39 are respectfully requested.

CONCLUSION

In view of the foregoing remarks, Applicants believe the application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. If there are any questions regarding the prosecution of this application, the Examiner is invited to contact the undersigned attorney at the phone number listed below to discuss the claims, the present amendment, or possible Examiner's Amendments that potentially place the present application in condition for allowance.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP

Thomas E. Kocovsky, Jr.
Reg. No. 28,383
1100 Superior Avenue
Seventh Floor
Cleveland, OH 44114-2518
(216) 861-5582